DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d1621b

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

cc: HFI-35/FOI S
DWA

December 30, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 19

Michael Rau
Vice President / General Manager
Multi-Clean, Incorporated
600 Cardigan Road
Shoreview, Minnesota 55126

Dear Mr. Rau:

During our inspection of your cosmetic and drug manufacturing facility located in Shoreview, MN, FDA Investigator Sharon Thoma observed serious deviations from Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations, Parts 210 and 211(GMP). A copy is enclosed for your information. The manufacture of antimicrobial soap in a facility which is not in compliance with GMP causes that drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our investigator documented non-compliance in all areas of GMP in the manufacturing of this product. Observed deviations include, but are not limited to:

1. Failure to test both raw material and finished product.
2. Failure to establish data to support expiration period.
3. Failure to calibrate equipment.
4. Failure to establish label controls.
5. Failure to establish or maintain a complaint file.

6. Failure to maintain adequate batch records.
7. Failure to assign unique lots numbers to raw material or finished product.
8. Failure to establish Standard Operation Procedures required by GMP.

These violations were described on Form FDA-483 delivered to you on December 10, 1996, by Ms. Thoma. A copy is enclosed for your convenience.

This identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely yours,

John Feldman
Director
Minneapolis District

LRM/ccl

Enclosures: 21 CFR Parts 210-211
FDA-483, 12/10/96

xc: Jerome Rau, President
Multi-Clean, Inc.
Minuteman International
111 South Rohlwing Road
Addison, IL 60101